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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/827,127	04/19/2004	Mitchell Kyle	44564.004	2311

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Intellectual Property Department
DEWITT ROSS & STEVENS, S.C.
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EXAMINER

HENRY, MICHAEL C

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 06/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/827,127

Applicant(s)

KYLE, MITCHELL

Examiner

Michael C. Henry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The following office action is a responsive to the Amendment filed, 03/25/05.

The amendment filed 03/25/05 affects the application, 10/827,127 as follows:

1. Claims 1-13 have been canceled. New claims 14-18 have been added. This leaves claims 14-18.

The responsive to applicants' arguments is contained herein below.

Claims 14-18 are pending in the application

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 provides for "the use of of zinc oxide and sodium heparin admixed with non-medicinal carriers " but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. In addition, it should be noted that "the use of" is not a statutory class of invention.

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Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 18 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peshoff (US 2002/0114847 A1) in combination with Edwards et al. (US 5,899,917).

In claim 14, applicant claims "A composition for treating insect bites and stings, comprising a therapeutically effective amount of zinc oxide and sodium heparin admixed with pharmaceutically acceptable non-medicinal carriers selected from the group consisting of carboxymethylcellulose, glycerin, polysorbate and water, wherein said effective amount for zinc oxide is in the range of 1-20 mg/g and for sodium heparin is in the range of

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100-300 USP units/g of said composition. Claim 15 is drawn to the composition according to claim 14, wherein said effective amount for zinc oxide is 5 mg/g and for sodium heparin is 160 USP units/g of said composition.

Peshoff discloses a composition comprising an effective amount of zinc oxide oxide (see claim 24, page 21 and 22). In addition, Peshoff discloses that zinc oxide promotes cleansing of wounds and decreases deterioration of existing wounds (see page 3, paragraph [0025]) and accelerates the healing of both chronic and acute wounds (see page 3, paragraph [0026]). Peshoff discloses also disclose that Zinc oxide has also been shown to maintain a constant level of zinc when applied to wounds as compared to salts of zinc. Re-epitheliaization is enhanced when zinc oxide is present. Inflammatory reaction has been shown to be reduced with adequate zinc concentration. Zinc oxide promotes cleansing of wounds and decreases deterioration of existing wounds. It has also been reported that the application of zinc oxide to wounds not only corrects the local zinc deficiency but also acts pharmacologically. Patients with diabetes mellitus have been noted as having zinc deficiencies related to impaired wound healing (see page 3, paragraph), [0025]).

Edwards et al. disclose that heparin and its derivatives promote the healing of wounds (col. 27, lines 17-23).

The difference between applicant's claimed composition and the composition taught by Peshoff is that applicant also uses a heparin derivative in their composition and a non-medicinal carrier. However, Edwards et al. disclose that heparin and its derivatives promote the healing of wounds (col. 27, lines 17-23), and the use of a non-medicinal carriers such as water in said composition is common in the art.

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It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Peshoff and Edwards et al., to have prepared a composition comprising a combination of a zinc derivative such as zinc oxide and a heparin derivative such as sodium heparin to be used to promote the healing of wounds, since the combination of compounds that are used to treat the same diseases or condition are well known in the art. More specifically, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

One having ordinary skill in the art would have been motivated, in view of Peshoff and Edwards et al., to prepare a composition comprising a combination of a zinc derivative such as zinc oxide and a heparin derivative such as sodium heparin to be used to promote the healing of wounds, because a skilled artisan would reasonably be expected to prepare a composition comprising a combination of the compounds taught by Peshoff and Edwards et al., to promote the healing of wounds based on type and/or severity of the viral infection or activity. It should be noted that the use of specific amounts of zinc oxide and heparin derivative depends factors such as severity and type of the wound treated.

Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saliba, Jr (US 4,879,282) in combination with Costello (US 5,874,094).

In claim 14, applicant claims "A composition for treating insect bites and stings, comprising a therapeutically effective amount of zinc oxide and sodium heparin admixed with pharmaceutically acceptable non-medicinal carriers selected from the group consisting of carboxymethylcellulose, glycerin, polysorbate and water, wherein said effective amount

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for zinc oxide is in the range of 1-20 mg/g and for sodium heparin is in the range of 100-300 USP units/g of said composition. Claim 15 is drawn to the composition according to claim 14, wherein said effective amount for zinc oxide is 5 mg/g and for sodium heparin is 160 USP units/g of said composition.

Saliba, Jr discloses a composition comprising an effective amount of sodium heparin which can be used for treating insect bites (see abstract and col. 7, lines 25-35).

Castello discloses that zinc oxide can be used to treat insect bites (see col. 4, lines 36-54).

The difference between applicant's claimed composition and the composition taught by Saliba, Jr is that applicant also uses a zinc oxide in their composition and a non-medicinal carrier. However, Castello discloses that zinc oxide can be used to treat insect bites, and the use of a non-medicinal carriers such as water in said composition is common in the art.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Saliba, Jr and Costello, to have prepared a composition comprising a combination of sodium heparin and zinc oxide to treat insect bites, since the combination of compounds that are used to treat the same diseases or condition are well known in the art. More specifically, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

One having ordinary skill in the art would have been motivated, in view of Saliba and Costello, to have prepare a composition comprising a combination of sodium heparin and zinc oxide to treat insect bites, because a skilled artisan would reasonably be expected to prepare a composition comprising a combination of the compounds taught by Saliba and costello, to treat

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insect bites based on type and/or severity of the insect bite. It should be noted that the use of specific amounts of sodium heparin and zinc oxide and depends factors such as severity and type of the insect bite treated.

Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saliba, Jr (US 4,879,282) in combination with Costello (US 5,874,094).

In claim 16, applicant claims "A method for treating insect bites and stings, comprising applying topically to the affected area an effective amount of zinc oxide and sodium heparin admixed with pharmaceutically acceptable non-medicinal carriers selected from the group consisting of carboxymethylcellulose, glycerin, polysorbate and water, wherein said effective amount for zinc oxide is in the range of 1-20 mg/g and for sodium heparin is in the range of 100-300 USP units/g of the admixture. Claim 17 is drawn to the composition according to claim 16, wherein said effective amount for zinc oxide is 5 mg/g and for sodium heparin is 160 USP units/g of said admixture.

Saliba, Jr discloses a method of treating insect bites comprising administering topically an effective amount of sodium heparin (see abstract and col. 7, lines 25-35).

Castello discloses that zinc oxide can be used to treat insect bites (see col. 4, lines 36-54).

The difference between applicant's claimed method and the method taught by Saliba, Jr is that applicant also uses a zinc oxide in their composition and a non-medicinal carrier. However, Castello discloses that zinc oxide can be used to treat insect bites, and the use of a non-medicinal carriers such as water in said composition is common in the art.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Saliba, Jr and Costello, to have used the method of Saliba, Jr to

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treat insect bites with a composition comprising a combination of sodium heparin and zinc oxide, since the combination of compounds that are used to treat the same diseases or condition are well known in the art. More specifically, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

One having ordinary skill in the art would have been motivated, in view of Saliba, Jr and Costello, to have use the method of Saliba, Jr to treat insect bites with a composition comprising a combination of sodium heparin and zinc oxide, because a skilled artisan would reasonably be expected to prepare a composition comprising a combination of the compounds taught by Saliba and Costello, to treat insect bites based on type and/or severity of the insect bite. It should be noted that the use of specific amounts of sodium heparin and zinc oxide and depends factors such as severity and type of the insect bite treated.

Response to Arguments

The applicant argument with respect to the references (Peshoff and Edwards et al.) are moot since applicant have canceled claims 1-13

The Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652.

The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

MCH

June 10, 2005.



ELVIS O. PRICE, PH.D.
PRIMARY EXAMINER